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| APPLICATION NO.                                       | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/568,348  | 02/21/2006  | Koji Sode            | 10921383USWO        | 2231             |
| HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902 |             |                      | EXAMINER            |                  |
|   |             |                      | GITOMER, RALPH J    |                  |
| MINNEAPOLIS, MN 55402-0902                            |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1657                |                  |
|   |             |                      |                     |                  |
|   |             |                      | MAIL DATE           | DELIVERY MODE    |
|   |             |                      | 05/16/2008          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  | Application No.   | Applicant(s)           |  |  |  |  |
|--|---|------------------------|--|--|--|--|
|  | 10/568,348  | SODE, KOJI             |  |  |  |  |
| Office Action Summary  | Examiner  | Art Unit               |  |  |  |  |
|  | Ralph Gitomer   | 1657                   |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply   | pears on the cover sheet with the c   | correspondence address |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                        |  |  |  |  |
| Status   |   |                        |  |  |  |  |
| 1)⊠ Responsive to communication(s) filed on 21 Fe  | ehruary 2006  |                        |  |  |  |  |
|  | · · · · · · · · · · · · · · · · · · ·   |                        |  |  |  |  |
| <u> </u>   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is |                        |  |  |  |  |
| ,  | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.               |                        |  |  |  |  |
| Disposition of Claims  |   |                        |  |  |  |  |
| 4)⊠ Claim(s) <u>1-20</u> is/are pending in the application.  | Claim(s) 1-20 is/are pending in the application   |                        |  |  |  |  |
| · · · · · · · · · · · · · · · · · · ·  | 4a) Of the above claim(s) is/are withdrawn from consideration.  |                        |  |  |  |  |
| 5) Claim(s) is/are allowed.  |   |                        |  |  |  |  |
| 6)⊠ Claim(s) <u>1-20</u> is/are rejected.  | · · · · · · · · · · · · · · · · · · ·   |                        |  |  |  |  |
| 7) Claim(s) is/are objected to.  |   |                        |  |  |  |  |
| 8) Claim(s) are subject to restriction and/o   | r election requirement.   |                        |  |  |  |  |
| Application Papers   |   |                        |  |  |  |  |
|  |   |                        |  |  |  |  |
| 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  |   |                        |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |                        |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.03(a).  |   |                        |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |                        |  |  |  |  |
| Priority under 35 U.S.C. § 119   |   |                        |  |  |  |  |
|  |   |                        |  |  |  |  |
| a) All b) Some * c) None of:   | 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).                 |                        |  |  |  |  |
| ·—   | <i>,</i> — <i>,</i> — ,—  |                        |  |  |  |  |
|  |   |                        |  |  |  |  |
| <ul><li>2. Certified copies of the priority documents have been received in Application No</li><li>3. Copies of the certified copies of the priority documents have been received in this National Stage</li></ul>   |   |                        |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |   |                        |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |   |                        |  |  |  |  |
| See the attached detailed Office action for a list of the certified copies not received.   |   |                        |  |  |  |  |
|  |   |                        |  |  |  |  |
| Attachment(s)  |   |                        |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  Paper No(s)/Mail Date   |   |                        |  |  |  |  |
| 3) 🔲 Information Disclosure Statement(s) (PTO/SB/08) 5) 🔲 Notice of Informal Patent Application  |   |                        |  |  |  |  |
| Paper No(s)/Mail Date 6) Other:  |   |                        |  |  |  |  |

The specification is objected to because of the following informalities, corrections are required. In the specification, on page 1, line 14, it is unclear what document may be intended. On page 2 line 5, in the first occurrence, "GOD" must be spelled out.

Please confirm the required enzyme as described on page 4 of the specification is commercially available to the public.

Although not claimed, it appears that the point of novelty is disclosed on page 10 of the specification, lines 19-23. A specific GDH eliminates the need for adding the electron mediator into the working electrode separately from the GDH. This enzyme has EC 1.1.1.47.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Yamaoka.

Yamaoka (2006/0035300) entitled "Method of Measuring Glucose concentration and Glucose Sensor with the Use of Glucose Dehydrogenase" teaches in paragraph 13, a glucose measuring method using GDH and cytochrome C and an electron carrier. In paragraph 20 the GDH has subunits. In paragraph 19 a glucose sensor with GDH from Burkholderia is taught. In paragraph 27 the same microorganism and enzyme as is

described in the present specification is set forth. In paragraph 71 the sensor is further described as having a short measurement time, wide range, high reproducibility

All the features of the claims are taught by Yamaoka for the same function as claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inose.

Inose (Biochimica et Biophysica Acta) entitled "Cloning and Expression of the Gene Encoding Catalytic Subunit of Thermostable Glucose Dehydrogenase from Burkholderia cepacia in E. coli" teaches on page 133 column 2, the same enzyme as presently claimed has future application as a biosensor component for determining glucose.

The claims differ from Inose in that they include additional electrode features.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the enzyme of Inose in a glucose sensor as suggested by Inose

where the glucose sensor has standard glucose sensor features as presently claimed.

All the features claimed are conventional in this art.

The following references are cited of interest:

Sode (7,094,585, 2006/0211094, 2006/0252123) teach GDH.

Yamaoka (2006/0094098) teaches GDH.

Hogen Esch (5,372,133) teaches glucose sensors.

Sode (7,244,600) entitled "Glucose Dehydrogenase" with a different inventive entity than the present application but a common inventor, and a PCT publication date of September 19, 2002, claiming priority to March 13, 2001, teaches a conventional glucose sensor with a conventional GDH.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/
Primary Examiner, Art Unit 1657

Ralph Gitomer Primary Examiner Art Unit 1657

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